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BECKMAN COULTER, INC.
P.O. BOX 169015
MAIL CODE 32-A02
MIAMI, FL 33116-9015

EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,477	MILLS ET AL.	
	Examiner	Art Unit	
	David A. Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESTRICTION/ELECTION

Claims 1-39 are pending.

Applicant's election of Group V (claims 28 and 34-39) in the reply filed on 7/27/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

During a telephone conversation with L. Haile on 10/3/06, the examiner indicated that no "kits" are recited in claim 28. A provisional election was made traverse to prosecute claims 34-39 of Group V. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 34-39 are under examination.

SPECIFICATION INFORMALITIES

The disclosure is objected to because of the following informalities:

In para. [0081] (as printed in US 2005/066958) It is believed that recitation of "The amount of third complex detected is proportional to the amount of solid analyte" is intended to read as --The amount of third complex detected is inversely proportional to the amount of solid analyte--. Compare to para. [0015]. One of skill would recognize para. [0015] as correct.

Likewise, In para. [0086] (as printed in US 2005/066958), It is believed that recitation of "The amount of third complex detected is proportional to the amount of solid analyte" is intended to read as --The amount of third complex detected is inversely proportional to the amount of solid analyte--. Compare to para. [0016]. One of skill would recognize para. [0016] as correct.

Appropriate correction is required.

112, SECOND ISSUES

Claims 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "cellular" in claims 34-39 is used by the claims to mean not only true cellular analytes, but also non-cellular analytes, such as viruses, virus-like particles, and colloidal particles. See para. [0023] of applicant's US PG publication 2005/0069958.

The accepted meaning of "cellular" is that true cellular structures have a cell wall or plasma membrane that separates their interior from the surrounding soluble medium. Non-cellular analytes, such as viruses, virus-like particles, and colloidal particles are not thus separated from their surrounding medium. The term "cellular" is indefinite because the specification does not clearly redefine the term.

Furthermore, applicant' disclosure confounds the considerations of what is a "cellular" and what is a "soluble" analyte. Para. [0023] lists a "virus" as a "cellular" analyte, while para. [0024] lists a "virus" as a "soluble" analyte. Because of this, and other recited species that likely overlap in the listings of what is considered to be "cellular" and what is considered to be a "soluble" analyte, one does not know the line of demarcation between a "cellular" and a "soluble" analyte. Therefore both the terms "cellular" and "soluble" are indefinite.

In claim 34, line 2 "said sample" lacks antecedent basis.

In claim 38, "said ligands capable of binding soluble analyte" lack antecedent basis.

Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such

omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are:

In claim 39, there is no functional relationship set forth for the "first ligand b)" nor for the "second ligand b)". More specifically, it is not clear if both or only one of these (and, if only one, which one) "binds a soluble analyte", as recited in claim 34, part b). If, for example, this claim is supposed to recite the components for the kit for practicing the method described in Fig. 3, then it is not clear what "ligands" of claim 39 would correspond to the biotin and the streptavidin in the Fig. Also, it is not clear why component c) includes "immobilized ligands capable of binding to said first ligand b) or second ligand b)." If this claim is supposed to recite the components for practicing the method of Fig. 3, then it would appear that component c) should only bind to the "second ligand b)."

112, FIRST ISSUES

Claims 34-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's description of solid phases (para [0049]-[0062]), assay formats, and examples refers entirely to beads as the solid phase. Furthermore, applicant's description of detecting the labels/markers is entirely directed to the detection of labels on cellular and bead-like/particulate entities, in order that one may simultaneously detect both a cellular and a soluble analyte. Applicant has given no description of how one might detect a cellular and a soluble analyte simultaneously when the solid phase is a test tube, test strip, test plate, sheet, rod or other type of solid phase medium commonly used in specific binding assays. Since the methodology for simultaneously detecting a cellular and a soluble analyte would differ when using solid phase media, other than beads, applicant was not in possession of any method, or kit to conduct such a method, except for the case in which the solid phase is constituted by beads.

Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

If one reads claim 39 for the case in which component c) includes "immobilized ligands capable of binding to said first ligand b)", applicant has not taught one how to use the components of the kit. Assuming that this claim is supposed to recite the components for practicing the method of Fig. 3, it would then appear that component c) should bind, rather, to the "second ligand b)."

Claims 34-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the case in which the solid phase capture medium is constituted with beads, does not reasonably provide enablement for the case in which the solid phase capture medium is constituted with any other type of solid phase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's teachings of solid phases (para [0049]-[0062]), assay formats, and examples refer entirely to beads as the solid phase. Furthermore, applicant's teaching of detecting the labels/markers is entirely directed to the detection of labels on cellular and bead-like/particulate entities, in order that one may simultaneously detect both a cellular and a soluble analyte. Applicant has given no teaching as to how one might detect a cellular and a soluble analyte simultaneously when the sample is in a test tube, test strip, test plate, sheet, rod or other type of solid phase medium commonly used in specific binding assays. Further the state of the art is such that it is not routine for one to detect a cellular and a soluble analyte simultaneously when using such other solid phase media. Thus undue experimentation would be required for one to use the invention, when the solid phase capture medium is other than beads.

Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling.

As indicated supra regarding 112, second paragraph, there is no functional relationship set forth for the "first ligand b)", nor for the "second ligand b)". The setting forth of such relationships is critical or essential to the practice of the invention, but is not included in the claim(s) is not enabled by the disclosure. See In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Also, as set forth supra under 112, second paragraph; the functional relationship of component c), which includes "immobilized ligands capable of binding to said first ligand b) or second ligand b)", is not accurately set forth for practicing the method of Fig. 3; since it would appear that component c) should only bind to the "second ligand b)."

ANTICIPATION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 34-36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Kardos et al (6,159,686, cited on Form 892).

Kardos et al teach assays for multiple analytes throughout their disclosure (e.g. col. 7, line 31-col. 8, line 2 and col. 22, line 59-col. 23, line 33). Examples of analytes are given at col. 11, lines 11-25 and in claim 3, which recites "or mixtures thereof." These listings clearly include what applicant considers to be both cellular and soluble analytes. Notes especially, the teachings at col. 23, lines 14-33 which describe a simultaneous assay which uses an antibody specific for "a lymphocyte CD 4 antigen" and a polynucleotide probe specific for an "HIV-1 sequence"; these are clearly "cellular" and "soluble" analytes according to applicant's own definitions. Kardos et al also teach the concept of kits (col. 48, lines 27-40 and claim 4).

With regard to the components that would be provided for the instant kits for a sandwich assay, as in claim 36, note col. 7, line 49-col. 2, line 2; col. 23, lines 34-65; and Fig. 20.

With regard to the components that would be provided for the instant kits for a competition assay, as in claim 38, note col. 7, line 49-col. 2, line 2; col. 23, lines 34-65; and Figs. 23-24.

Note, also, the variations in labeling (e.g. direct vs. indirect) taught at col. 19, line 66-col. 22, line 11.

From the above, the components of the kits of claims 34-36 and 38 are shown by Kardos et al.

OBVIOUSNESS

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez-Caballero et al (cited on Form 1449 of 10/12/04) in view of Rittershaus et al (5,426,029, cited on Form 1449) and as necessary Kardos et al.

The publication date of the primary reference is 2003. It is not possible to determine whether this predates applicant's filing date of 9/26/03. In the absence of evidence to the contrary, the reference is assumed to predate; an obviousness rejection based on 102(a) is thus stated as follows.

Rodriguez-Caballero et al teach a method in which the components of instant kit claims 34-36 are used to assay for TNF-alpha, as a cellular component, and for secreted cytokine(s), as soluble component(s). Reagents in step 9 (p 9.21.3) correspond to instant component c). Reagents in step 13 (p 9.21.3) correspond to instant component b). Reagents in step 17 (p 9.21.4) correspond to instant component a). Rodriguez-Caballero et al do not teach a kit; however, Rittershaus et al teach that provision of reagents necessary to assay for total or secreted T-cell products in kit form are conventional in the art; see col. 26, line 11-col. 27, line 5 and col. 36, lines 13-31. Thus provision of the reagents taught by Rodriguez-Caballero et al in kit form would have been obvious. Kardos et al are relied upon to the extent necessary for the teaching that a kit comprises "all of the essential ingredients required to conduct the desired assay" (col. 48, lines 27-30). One or more containers for reagents, as in instant claim 35, are inherent to any kit (e.g. Kardos et al at col. 48, lines 34-39).

Claims 34-37 are rejected under 35 U.S.C. 103(a) as obvious over Spies et al (2005/0233391, cited on Form 892), alone or in view of Kardos et al.

The rejection is based upon 102(e). The effective filing date of the reference goes back at least to the 4/23/03 filing date of PCT application PCT/US03/12299; furthermore provisional application 60/374,442 supports the portions of the disclosure relied upon by the examiner.

Spies et al disclose assaying for both soluble MIC and for tumor cell bound MIC – e.g. see para. [0021], [0051], [0064], [0194]-[0195] and claim 34. They disclose kits having components to conduct the assays – e.g. see para. [0025], [0034], [0212]-[0220]. Since it is conventional to provide all reagents in a kit (Kardos et al at col. 48, lines 27-30), provision of the necessary reagents to detect both soluble MIC and tumor cell bound MIC would have been obvious.

Regarding instant component a), note teachings at para. [0139] and [0275], wherein a biotinylated anti-MIC mAb and Streptavidin-FITC are used to detect cell bound MIC. Regarding instant components b) and c) and instant claims 36-37, note the teachings of a sandwich assay for soluble MIC (e.g. para. [0019], [0197], [0208], [0262]) and of a competitive/one-site immunometric assay (e.g. para. [0199]).

Regarding the containers of claim 35 note para. [0219].

Claims 34-36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ochoa et al (5,965,366, cited on Form 892).

Ochoa et al determine various indices, or ratios of markers, which give a measure of T-cell function. For example, they determine the ratio of two soluble analyte markers, such as the ratio of a TH1 lymphokine to a TH2 lymphokine – e.g. col. 10, lines 21-35; col. 11, lines 34-44. These lymphokines are detected by an ELISA test (col. 21, lines 21-50).

Ochoa et al also determine the indices/ratios of a TCR complex subunit protein, such as CD3-epsilon or CD3-zeta, to the amount of another TCR complex protein – e.g. col. 10, line 58-col. 11, line 34. These proteins are determined by an ELISA sandwich assay (col. 17, line 65-col. 20, line 24). Alternatively these proteins are detected in intact, permeabilized cells via indirect immunofluorescence – e.g. col. 20, line 25-col. 21, line 19. These proteins are properly considered to be "cellular" since they are obtained from detergent lysed cells (col. 17, lines 65-67); in such case, they are present in a colloidal complex of proteins associated with one another (see applicant's disclosure at para. [0023]). Likewise, these proteins are "cellular" since they are detected in intact, permeabilized cells (col. 20, lines 25-34).

In a similar manner, Ochoa et al point to determining a ratio of cytoplasmic to nuclear levels of an intracellular protein such as p65 or c-rel (e.g. col. 11, line 45-col. 12, line 34).

Ochoa et al teach that in many cases it may be useful to determine, more than one index/ratio of T-cell function – e.g. col. 7, lines 39-55; col. 16, lines 8-13. Ochoa et

al furthermore teach kits containing reagents to determine one or more ratios of markers – e.g col. 12, line 66-col. 13, line 40; col. 15, lines 26-62. While Ochoa et al do not point out specific combinations of ratios that one should obtain, it is clear that any kit having the reagents for conducting an ELISA test for soluble markers, such as TH1 or TH2 cytokines, and the reagents for detecting intracellular markers, such as a TCR complex subunit protein, p65, or c-rel, would have all of the reagents recited in instant claim 34. The container of claim 35 is disclosed at col. 13, lines 3-5.

Claims 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mikecz et al in view of Siegel et al (6,001,356 and 5,272,258, cited on Form 892) and if necessary Kardos et al.

Mikecz et al motivate the testing of both cell surface CD44 and a soluble acute phase protein, as a means of monitoring therapy of an autoimmune disease (col. 8, lines 37-43). Siegel et al show antibodies and immunoassays for assaying for soluble C-reactive protein (CRP), which is an acute phase protein; it is taken that one would want to detect the neo-CRP disclosed by Mikecz, since this is associated with rheumatoid arthritis (col. 2, lines 10-12). Siegel et al disclose numerous immunoassay formats, such as competitive, one-site immunometric, and two-site immunometric (e.g. col. 6, line 65-col. 7, line 30) and kits to conduct such (col. 5, lines 26-30; col. 8, lines 47-61). Since it is conventional to supply all reagents necessary in kit form (Kardos et al at col. 48, lines 27-30), it would have been obvious to have supplied the anti-CD44 antibody disclosed by Milcez et al and the reagents to test for soluble CRP disclosed by Siegel et al in one kit. Such a kit would clearly have the components of instant claim 34. The container of claim 35 is disclosed by Siegel et al at col. 8, lines 49-53.

Regarding claim 36, the components disclosed by Siegel et al for a two-site immunometric (sandwich) assay for CRP (col. 7, lines 21-30) are consistent with those recited.

Regarding claim 37, the components disclosed by Siegel et al for a one-site immunometric assay for CRP (col. 7, lines 13-20) are consistent with those recited.

Regarding claim 38, the components disclosed by Siegel et al for a competitive assay for CRP (col. 7, lines 7-12) are consistent with those recited.

Claims 34-36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rittershaus et al (5,426,029, cited on Form 1449).

Rittershaus et al disclose immunoassays for determining the level of soluble/released forms of T-cell surface antigens, as markers of diseases/disorders. They also disclose immunoassays that detect both soluble and cell lysate forms of a marker. They particularly point to sandwich immunoassays (col. 17, lines 60-65) as well as to other immunoassay formats (col. 26, lines 11-45). They disclose kits therefore (col. 26, line 64-col. 27, line 5 and col. 36, lines 13-31). They point to kits for testing for combinations of markers (col. 27, lines 1-5). They teach testing for multiple soluble markers –e.g. col. 47, line 36-col.48, line 44).

If one considers a kit that would have the components for assays for soluble CD4 and at least one other soluble marker, one would have the instant components, irrespective of the fact that the kit has components for assaying for two soluble components. Note that the disclosed assay for soluble CD4 can use R2B7 as a capture antibody and leu-3a as a detection (biotin-labeled) antibody; see col. 41, lines 1-5 and notation under Table XIII at col. 44. It is to be noted that the biotin-labeled Leu3a antibody recognizes cell surface CD4 and can also be used in cell phenotyping (e.g. see col. 43, lines 26-31); thus the biotin-labeled Leu3a antibody could be used to test for cellular CD4, irrespective of the fact that it would have been provided to test for soluble CD4. This labeled antibody plus the components to test for another soluble marker by a sandwich assay would have all components of instant claims 34-36. The fact that Rittershaus et al would also provide the R2B7 capture antibody for CD4 is not relevant, since "comprising" language of the instant claims permit kits to contain more than what is explicitly recited.

Claims 34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kardos et al in view of Siegel et al.

Kardos et al have been noted supra for anticipating the instant kits having the components for sandwich and competitive assays, as in instant claims 36 and 38. Kardos et al teach that various art known binding assay formats may be employed (e.g. col. 19, line 66-col, 22, line11; col. 45, lines 13-23). Siegel et al have been noted supra for teaching that the sandwich, one-site immunometric, and competitive assays are all alternative ways of assaying for a soluble analyte. It thus would have been obvious that the components to conduct a one-site immunometric assay, as in instant claim 37 would be provided in kit form, in order to conduct the multiple analyte assays of Kardos et al.

Claims 34 and 38 are rejected under 35 U.S.C. 103(a) as obvious over Spies et al (2005/0233391, cited on Form 892), in view of Siegel et al.

Spies et al have been noted supra for anticipating the instant kits having the components for sandwich and competitive/one-site immunometric assays, as in instant claims 36-37. Spies et al teach that various art known binding assay formats may be employed (e.g. para. {0193]-[0201]). Siegel et al have been noted supra for teaching that the sandwich, one-site immunometric, and competitive assays are all alternative ways of assaying for a soluble analyte. It thus would have been obvious that the components to conduct a competitive assay, as in instant claim 38 would be provided in kit form, in order to conduct the assays of Spies et al.

Claims 34 and 37-38 are rejected under 35 U.S.C. 103(a) as obvious over Ochoa et al in view of Siegel et al.

Ochoa et al have been noted supra for anticipating the instant kits having the components for a sandwich assay, as in instant claim 36. Ochoa et al teach that various art known binding assay formats may be employed (e.g. col. 12, lines 57—65). Siegel et al have been noted supra for teaching that the sandwich, one-site immunometric, and competitive assays are all alternative ways of assaying for a soluble analyte. It thus would have been obvious that the components to conduct a one-site immunometric

assay or a competitive assay, as in instant claims 37-38, would be provided in kit form, in order to conduct the multiple assays of Ochoa et al.

Claims 34 and 37-38 are rejected under 35 U.S.C. 103(a) as obvious over Rittershaus et al (5,426,029, cited on Form 1449) in view of Siegel et al.

Rittershaus et al have been noted supra for anticipating the instant kits having the components for a sandwich assay, as in instant claim 36. Rittershaus et al teach that various art known binding assay formats may be employed (e.g. col. 26, lines 13—27), including those for sandwich and competitive assays. Siegel et al have been noted supra for teaching that the sandwich, one-site immunometric, and competitive assays are all alternative ways of assaying for a soluble analyte. It thus would have been obvious that the components to conduct a one-site immunometric assay or a competitive assay, as in instant claims 37-38 would be provided in kit form, in order to conduct the multiple assays of Rittershaus et al.

Claims 34 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kardos et al, Ochoa et al or Rittershaus et al, any in view of Primus (4,737,453 cited on Form 892).

Each of Kardos et al, Ochoa et al and Rittershaus et al have been noted supra for anticipating the instant kit having the components for a sandwich assay, as in claim 36. Assuming that instant claim 39 is intended to recite the components that would be used to from a complex as shown in Fig. 3, Primus shows these components and teaches kits containing such. In Primus the insoluble phase having a bound "separation specific binding substance" corresponds to instant component c). The "separation specific binding substance" can be, for example, an anti-isotype or anti-hapten antibody (col. 2, lines 33-46) or avidin (col. 4, lines 11-17). The "separation specific binding substance" can thus bind to an antibody having a particular isotype, or to an antibody conjugated to a hapten or biotin, in order to provide for a capture antibody in a sandwich assay format. Primus teaches that his assay format offers advantages over the conventional sandwich assay format (e.g. col. 2, lines 26-33). One would thus have

been motivated to provide a kit having the components to detect the soluble analyte(s) of any of the primary references, according to the modified version of the sandwich immunoassay taught by Primus.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mikecz et al in view of Siegel et al and if necessary Kardos et al, as applied to claim 34 above, and further in view of Primus.

Mikecz et al has been cited supra in view of Siegel et al for rendering obvious the instant kit having the components for a sandwich assay, as in claim 36. Assuming that instant claim 39 is intended to recite the components that would be used to from a complex as shown in Fig. 3, Primus shows these components and teaches kits containing such. In Primus the insoluble phase having a bound "separation specific binding substance" corresponds to instant component c). The "separation specific binding substance" can be, for example, an anti-isotype or anti-hapten antibody (col. 2, lines 33-46) or avidin (col. 4, lines 11-17). The "separation specific binding substance" can thus bind to an antibody having a particular isotype, or to an antibody conjugated to a hapten or biotin, in order to provide for a capture antibody in a sandwich assay format. Primus teaches that his assay format offers advantages over the conventional sandwich assay format (e.g. col. 2, lines 26-33). One would thus have been motivated to provide a kit having the components to detect the soluble acute phase protein in the assay of Mikecz et al, according to the modified version of the sandwich immunoassay taught by Primus.

DOUBLE PATENTING

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 34-35 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 87-88 of copending Application No. 10/515,073. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 36-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 87-88 of copending Application No. 10/515,073 in view of Siegel et al.

Siegel et al teach that various immunoassay formats, such as sandwich/two-site immunometric, one-site immunometric and competitive, are known and are applicable to the detection of soluble molecules. Thus it would be obvious to provide the components for detecting the instant soluble analyte, as recited in instant claims 36-39, in the kit of copending application 10/515,073.

This is a provisional obviousness-type double patenting rejection.

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is

571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 10/14/06 DAS

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 1644